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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/030,972
Filing Date: January 15, 2002
Appellant(s): ABEL ET AL.

Mr. Jay Williams
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 19 December 2007 appealing from the Office action mailed 19 June 2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(**8) Evidence Relied Upon**

No evidence is relied upon by the examiner in the rejection of the claims under appeal.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-34, 38-40, 42-47, 81-84 and 86-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neuschäfer et al. (WO 96/35940) in view of Coassin et al. (US 6,660,233).

Neuschäfer et al. teach a device comprising: a sensor platform having a planar optical waveguide (pg. 13, last paragraph-pg. 14, line 4), and a sealing layer forming a tight seal with a sealing medium with the planar optical waveguide (a cover is part of a sealing layer that is glued to the sensor platform to form a unit, pg. 29, lines 1-17; pg. 13, last paragraph-pg. 14, line 5); a plurality of recesses opening at least towards the sensor platform (a cover which is part of the sealing layer has recesses, central cut out portions, comprising inlet and outlet openings for solutions, pg. 14, lines 6-12), each of the recesses forming a corresponding sample compartment in a 2-dimensional arrangement wherein at

least two sample compartments are in a length direction of the array and at least two sample compartments are in a width direction of the array (central cut out portions form a flowthrough cell, which is the sample compartment, the sample compartments are formed in a 2-dimensional arrangement, pg. 14, lines 6-12, 7, Fig. 5a and 5b), wherein each of the sample compartments comprise different biological recognition elements, for specific recognition and binding of different analyte (pg. 14, lines 11-12; pg. 21, lines 19-24; immobilized recognition elements that are specific to different analyte indicates that the recognition elements are different, pg. 13, lines 11-16; pg. 8, lines 22-24; pg. 18, lines 3-6; pg. 34, line 26-pg. 25, line 5; pg. 45, lines 3-5) and are immobilized in 5 to 50 discrete measurement areas, which encompasses the recited five or more, in a two-dimensional array on the planar optical waveguide (number of individual waveguiding regions, pg. 13, lines 7-8; recognition elements immobilized on waveguiding regions, pg. 14, lines 11-12; detection regions, pg. 13, lines 21-22), the measurement areas are in optical interaction with an excitation light emanating from the optical waveguide as part of the sensor platform which forms a demarcation of the sample compartments (pg. 7, lines 18-19; pg. 8, lines 22-24; pg. 17, lines 5-6), wherein the sample compartments are operable such that samples received therein are removable therefrom and further sample solutions are receivable therein (outlet indicates that samples are removable and further samples are receivable, pg. 14, lines 8-10). Neuschäfer et al. fail to teach the measurement areas being arranged in an array wherein there are at least two measurement areas in a width direction of the array and at least two measurement areas in a length direction of the array.

Coassin et al. teach an array on a waveguide (col. 1, lines 60-65) having an array of measurement areas wherein the array has a linear arrangement of immobilized biological reactants (col. 2, lines 40-44) or has at least two measurement areas in a width direction

and at least two measurement areas in a length direction (col. 2, lines 44-48), in order to provide distinct regions of active sites for detection of target biomolecules.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the device of Neuschäfer et al., an arrangement having at least two measurement areas in a width direction of an array and two measurement areas in a length direction of an array as taught by Coassin et al. It would have been obvious because Coassin et al. teach that either a linear arrangement of measurement areas or a two-dimensional array arrangement with at least two measurement areas in both a length and width direction are well known in the art to produce rapid and equivalent detection results of a target biomolecule, and therefore either array arrangement of measurement areas can be used for detection of target biomolecules. Furthermore, rearranging the measurement areas from a linear array to an array with more than one measurement area in the length and width directions would have been obvious because it has been held that rearranging parts of an invention involves only routine skill in the art. See *In re Japikse,* 86 USPQ 70.

Regarding claims 2 and 3, Neuschäfer et al. teach one measurement area in each of the sample compartments used for referencing (quality control, pg. 36, lines 23-24). Neuschäfer et al. also teach the referencing measurement areas reference same chemical parameters in a number of sample compartments distributed over the sensor platform (same control molecules, used for referencing, are immobilized in strips on five regions, pg. 36, lines 25-26). Neuschäfer et al. do not specifically teach lateral distribution of the chemical parameters over the sensor platform. However, such a limitation is drawn to intended use of referencing measurement areas and do not require any further product limitations. Therefore, since the device of Neuschäfer et al. comprise the limitations recited

in claims 1 and 2, the device of Neuschäfer et al. would be capable of providing such determination of chemical parameters.

With respect to claim 4, Neuschäfer et al. teach measurement areas in optical interaction with an evanescent field of the excitation light guided in the planar optical waveguide (pg. 6, last line-pg. 7, line 3).

Regarding claims 5 and 6, Neuschäfer et al. teach the planar optical waveguide being self-supporting (pg. 5, lines 24-29) and part of the sensor platform being a multi-mode or single-mode waveguide comprising glass (pg. 15, line 10), which is optically transparent at the excitation wavelength (pg. 15, lines 13-14).

With respect to claims 7-13, Neuschäfer et al. teach the planar optical film waveguide comprising a first optically transparent layer, a waveguiding layer, on a second optically transparent layer, made of glass, wherein the second optically transparent layer has a lower refractive index than the first layer (pg. 10, lines 12-17; pg. 15, lines 19-22) and wherein the refractive index of the first optically transparent layer is higher than 2.0 (pg. 16, lines 2-3), which encompasses the recited greater than 1.8, and is made of TiO_2 (pg. 15, lines 4-5). Neuschäfer et al. also teach the thickness of the first optically transparent layer between 40 and 1000 nm (pg. 15, lines 7-8), which encompasses the recited between 40 and 300 nm. Neuschäfer et al. also teach an additional optically transparent layer located between the first and second optically transparent layers, and in contact with the first optically transparent layer (substrate is covered with thin layer, which indicates contact, pg. 15, lines 18-20), and having a thickness of less than 10,000 nm (pg. 15, lines 17-18), which encompasses the recited range of 5-10,000 nm, wherein the purpose of the additional layer is to reduce the surface roughness below the first optically transparent layer (pg. 15, lines 18-22).

Regarding claims 14-16, Neuschäfer et al. teach an the device further comprising an adhesion-promoting layer deposited on the first optically transparent layer for the immobilizing biological recognition elements (pg. 19, lines 14-16), having a thickness of less than 50 nm (pg. 19, lines 17-18), which is encompassed by the recited less than 200 nm, and a comprising chemical compounds of silanes (pg. 12, lines 15-20).

With respect to claims 17-18 and 81, Neuschäfer et al. teach measurement areas generated by deposition of biological elements on the sensor platform (Fig. 3-5; pg. 13, last paragraph-pg. 14, line 2; pg. 18, lines 12-13). Although Neuschäfer et al. do not specifically teach the areas generated by deposition of biological recognition elements, such a limitation does not appear to physically further limit the product recited in claims 1 and 17. It is unclear what product limitations are set forth by areas generated by laterally selective deposition, and since the same product limitations are taught by Neuschäfer et al. as recited in claims 1 and 17, the product of Neuschäfer et al. would be capable of comprising measurement areas generated by deposition of biological elements. Neuschäfer et al. teach a method of deposition comprising ink jet spotting (pg. 18, lines 15-21).

Regarding claims 19 and 20, Neuschäfer et al. teach a biological recognition element being nucleic acids (pg. 21, lines 19-24), including DNA which comes from a cell and is considered a cell fragment.

With respect to claims 21-22, Neuschäfer et al. teach "chemically neutral" compounds such as bovine serum albumin, to minimize nonspecific binding (pg. 37, lines 23-29; pg. 40, lines).

Regarding claims 23-26, Neuschäfer et al. teach the first optically transparent layer having at least one grating structure formed therein for incoupling excitation light to the measurement areas (pg. 16, lines 22-25), and the first optically transparent layer having at least one grating structure formed therein for outcoupling of light into the first optically

transparent layer (pg. 17, lines 5-13). Neuschäfer et al. also teach the incoupling and out coupling grating structures interchangeable with respect to incoupling and outcoupling (pg. 17, lines 6-7).

With respect to claims 27-29, Neuschäfer et al. teach grating structures having a period of 200 nm – 1000 nm and a grating modulation depth of 3-100 nm (pg. 16, last paragraph), wherein the ration of the grating modulation dept to thickness of the first optically transparent layer is equal to or smaller than 0.2 (pg. 16, lines 11-12). Neuschäfer et al. further teach grating structures being rectangular with a periodic modulation of the refractive index in the planar optically transparent layer (rectangular, pg. 16, lines 16-17).

Regarding claim 30, Neuschäfer et al. teach a thin metal layer, gold, deposited between the first optically transparent layer and the immobilized biological recognition elements, wherein the thickness of the metal can be excited at a luminescence wavelength (pg. 11, lines 11-15).

With respect to claims 31-34, Neuschäfer et al. teach a grating structure having a diffractive grating with a uniform period (pg. 16, last paragraph) or a multi-diffractive grating (1-3 modes is a multi-diffractive grating, pg. 18, lines 1-2). Neuschäfer et al. further teach the incoupling and outcoupling grating structures located outside a region of the sample compartments (grating located in and out of sample compartment, 3,3', Fig. 6; pg. 9, lines 23-24) and grating structures extend over at least a portion of the sample compartments (one periodicity indicates one grating structure over all sample compartments; pg. 16, last paragraph).

Regarding claims 38, 39, 82 and 83, Neuschäfer et al. teach a sealing material, comprising polysiloxane (pg. 12, lines 15-20), and is self-adhesive (pg. 34, lines 4-7).

With respect to claims 40, 42, 84 and 86, Neuschäfer et al. teach 2-100 measurement areas in one sample compartment (pg. 13, lines 22-23), which is

encompassed by the recited 2-1000 measurement areas. Neuschäfer et al. also teach the sample compartments having a volume of 0.07 ml (pg. 34, line 5), which is encompassed by the recited 100 nl-1ml.

Regarding claims 43 and 87, Neuschäfer et al. the device comprising sample compartments closed at a side facing away from the sensor platform except for inlet and outlet openings for sully and removal of samples (Fig. 5b; pg. 14, lines 6-12). Neuschäfer et al. fail to teach supply or removal of samples performed in a closed flow-through system, wherein common inlet and outlet openings are addressed row by row or column by column. However, such limitations do not appear to further limit the product limitations recited in claims 1, 43 and 87. Therefore, since Neuschäfer et al. teach the product limitations recited in claims 1, 43 and 87, the device of Neuschäfer et al. would be capable of performing such supply or removal of samples.

With respect to claims 44 and 88, Neuschäfer et al. fail to teach supply of samples affected by pressure differences or electric potentials. However, such a limitation does not appear to provide further product limitations to the product of claims 1 and 44. Therefore since Neuschäfer et al. teach the recited product limitations of claims 1 and 44, the device of Neuschäfer et al. would be capable of affecting the sample supply with the recited pressure differences or electric potentials.

Regarding claims 45-47 and 89-91, Neuschäfer et al. teach sample compartments having openings for locally addressed supply or removal of samples or other reagents at the side facing away from the sensor platform (inlet and outlet openings for solutions, pg. 14, lines 6-12). Neuschäfer et al. further teach compartments provided for reagents (reagents are contained in a compartment when introduced into the flow-through device, pg. 36, lines 8-10). Neuschäfer et al. also teach mechanically recognizable marks are provided on the sensor platform, in order to facilitate the adjustment in an optical system (depression cut

for waveguide so waveguiding layer faces the cannels and facilitates optical detection, pg. 37, lines 7-13).

2. Claims 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neuschäfer et al. in view of Coassin et al., as applied to claim 1, further in view of Hashimoto et al. (US 6,480,639).

Neuschäfer et al. in view of Coassin et al., as applied to claim 23, teach a device comprising a tight sealing layer, but fail to teach the material being optically transparent or optically absorbent.

Hashimoto et al. teach a sealing layer being optically transparent or absorbent (col. 16, lines 54-63), in order to block leakage lights from the light emitting device.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the device of Neuschäfer et al. in view of Coassin et al., an absorbent or transparent sealing layer as taught by Hashimoto et al., in order to more effectively seal the optical device and fix optical fibers.

Hashimoto et al. also teach a 2 layer system wherein a first layer that is transparent to excitation radiation is brought into contact with a sensor platform (col. 16, line 54-57), and a second layer absorbent in a spectral range of the excitation radiation is present and located remotely from the sensor platform (col. 16, lines 58-63).

3. Claims 41 and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neuschäfer et al. (WO 96/35940) in view of Coassin et al. (US 6,660,233).

Neuschäfer et al. in view of Coassin et al., as applied to claim 1, teach a device comprising a sample compartment occupying an area of 9 mm^2 (pg. 36, last 2 lines). Neuschäfer et al. fail to teach an area of 0.001-6 mm^2. However, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value for a result effective variable. "[W]here the general conditions of a claim are

disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation" Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Since applicant has not disclosed that the specific limitations recited in instant claims 41 and 85 are for any particular purpose or solve any stated problem, and the prior art teaches that the measurement area can be varied in order to accommodate different sample volumes, absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by the prior art by normal optimization procedures know in the flow-through device art.

(10) Response to Argument

At page 6, appellant argues that Neuschäfer et al. fails to teach that each of the strip-like waveguiding regions has recognition elements arranged with at least two measurement areas in a length direction and at least two measurement areas in a width direction. Appellant's argument is not persuasive because Neuschäfer et al. is not relied upon for teaching two measurement areas in a length direction and two measurement areas in a width direction. Neuschäfer et al. teach the configuration of measurement areas in a single sample compartment shown in Fig. 5a as being an array of measurement areas having at least two measurement areas in a length direction, but only one measurement area in a width direction. For simplicity, a single sample compartment is shown below:

1. Single sample compartment taught by Neuschäfer

At page 7, appellant argues that Neuschäfer et al. fail to teach that each strip-like waveguiding region has different biological or biochemical recognition elements immobilized in five or more discrete measurement areas. Appellant's argument is not persuasive because at page 18, lines 3-6, Neuschäfer et al. teach that different specific binding partners are immobilized on the surface waveguiding regions (waveguiding regions are the measurement areas, Fig. 5a shows more than five discrete measurement areas, and if a different specific binding partner is present in each area, different biological recognition elements are immobilized in at least 5 measurement areas).

At page 7, appellant further argues that the different waveguide (detection) regions of Neuschäfer et al. are optically "isolated" against each other, and by contrast, in the present invention there is no "optical isolation" of the detection regions and the light from the waveguide is isotropically emitted. Appellant's argument is not persuasive because this limitation is not recited by the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

At pages 7-8, appellant argues that Coassin does not disclose or suggest an array on a waveguide having an array of measurement areas, wherein the array has a linear arrangement of immobilized reactants. Appellant's argument is not persuasive because Coassin is relied upon only for its arrangement of measurement areas and is not relied upon for teaching a waveguide. Neuschäfer et al. is relied upon for teaching a waveguide having measurement areas.

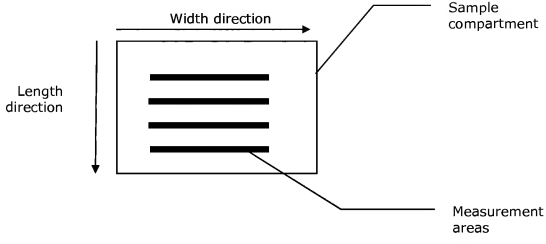
At page 8, appellant argues that the "2-dimensional bioarray" of Coassin is plunged into a hole of a 96 well plate and is therefore <u>different</u> from the present invention. Appellant's argument is not persuasive because Coassin teaches two different types of

arrangements for arrays having immobilized biological recognition elements. Coassin is not relied upon for teaching any elements of the present invention except arrangement of biological recognition elements on a substrate.

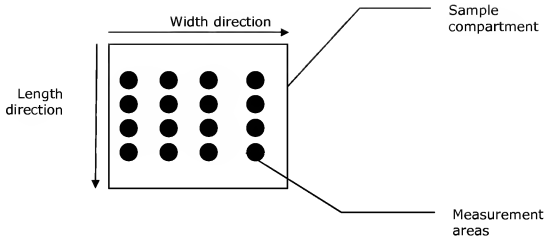
At pages 8-9, appellant argues that Coassin fails to suggest the present invention because no information about the technical realization is provided in the reference and it is unclear how a waveguide should be positioned on a pipette tip within which the bioarray is affixed in order to provide a workable invention and to arrive at the present invention. Appellant further argues that Neuschäfer does not rectify this deficiency. Appellant's arguments are not persuasive because the rejected claims are obvious over the *combination* of Neuschäfer and Coassin, and the rejection is not based upon affixing the waveguide of Neuschäfer on the pipette tip of Coassin. The rejection is based on combining the structure of Neuschäfer having measurement areas with the measurement area array of Coassin wherein the measurement areas are arranged with at least two measurement areas in both the length and width direction. At column 2, lines 40-48, Coassin teaches that an array of immobilized biological recognition elements (measurement areas) that may be arranged in one of two functionally equivalent ways: the first arrangement with measurement areas arranged in a strip-like configuration (Coassin, Fig. 2) and the second arrangement with measurement areas arranged in a 2-dimensional array with at least two measurement areas in the width direction and at least two measurement areas in the length direction (Coassin, Fig. 3). Coassin teaches the two different arrangements of arrays being functionally equivalent. It would have been obvious to one having ordinary skill in the art to arrange the measurement areas in either the strip-like formation of (Coassin, Fig. 2 or Neuschäfer, Fig. 5a) or in the 2-dimensional array (Coassin, Fig. 3) since the arrangements are functional equivalents according to Coassin.

The two functionally equivalent arrangements of measurement areas in a sample compartment as taught by Coassin are shown below:

2. Strip-like arrangement taught by Coassin

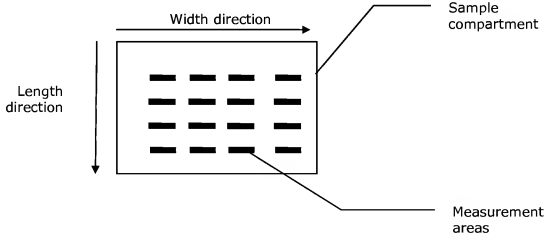


3. 2-Dimensional array arrangement taught by Coassin



The combination of Neuschäfer et al. and Coassin yields a sample compartment with measurement areas arranged as shown below:

4. Combination of strip regions of Neuschäfer (1.) and 2-D array of Coassin (3.)



The combination of Neuschäfer and Coassin provides at least two measurement areas in a width direction and at least two measurement areas in a length direction.

At page 9, appellant argues that Neuschäfer and Coassin lack predictability and a reasonable expectation of success of combining and/or modifying their teachings to arrive at the present invention. Appellant's arguments are not persuasive for the reasons stated above. The combination of prior art references is proper because Coassin is relied upon only for teaching functionally equivalent strip-like and 2-dimensional array arrangements of measurement areas in a sample compartment. Therefore the motivation to combine is based on functional equivalence taught by the prior art.

Appellant does not present any new arguments regarding the rejections of dependent claims 2-47 and 81-91.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Melanie Yu/
Examiner, Art Unit 1641

Conferees:

/Long V Le/
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